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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,712

09/19/2005

Wei Tian

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,712

Applicant(s)

TIAN ET AL.

Examiner

GiGi Huang

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on November 19, 2007 is acknowledged. The restriction is traversed on the grounds for meeting burden. This is not found persuasive because the instant case is submitted under 35 U.S.C. 371, the Unity of Invention practice in MPEP §1850 and MPEP §1893.03(d) was followed, not restriction practice. Thus the criteria for burden stated in MPEP §803 for national applications filed under 35 U.S.C. 111(a) does not apply (MPEP §801). The lack of unity has been addressed in the previous action. As the technical feature did not contribute over the art, the restriction was applied appropriately.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application

2. Applicant has elected Group I in response to restriction requirement for the examination.

Due to restriction, based on election of Group I, claims 8-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-7 are present for examination at this time.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 4 fails to further limit the parent claim 1.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation "sugar", and the independent claim 1 recites "highly water-soluble sugar" which is the narrower statement of the range/limitation.

6. Claim 7 recites the limitation "the granules" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b), as being anticipated by Gergely (WO 01/51026).

Gergely teaches the use and compositions utilizing a solution of water, sugar, and citric acid as a binder for granulation of mannitol and other excipients (Page 11, Example 1). Gergely also teaches examples utilizing the solution with sorbitol and sucrose rather than sugar (also known as sucrose or saccharose) with the citric acid as a binder for granulation (Page 11-16, Example 1-2,4).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

9. Claims 1-6 are rejected under 35 U.S.C. 102(b), as being anticipated by Wokoff et al. (U.S. Pat. No. 3511914).

Wokoff et al. teaches the wet granulation and tableting compositions utilizing a highly water-soluble sugar and citric acid with water (or alcohol or hydro-alcoholic mixture) inherently binding the components during granulation for granules that are eventually dried and compressed into tablets. A method of wet mixing and spray drying to form the granules for tableting is also taught (Col. 3, lines 5-50). Confectioner's sugar (also known as sucrose or saccharose) and sucaryl-saccharin (a combination of cyclamate and saccharin) are used in the examples. Cyclamate is a highly water soluble

sugar, and fulfills the claim ratios (as the routine cyclamate: saccharin ratio mix is 10:1). Wokoff also teaches that the specific medicaments and specific excipients employed in the examples are not critical to the invention and that many variations in these ingredients will suggest themselves to those skilled in the art. Wokoff also teaches that such variations are to be the full equivalent of the formulations taught by Wokoff et al. (Col. 3, lines 65-68, Col. 4, lines 1-5).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

10. Claims 1-7 are rejected under 35 U.S.C. 102(b), as being anticipated by Opakunle et al. (The granulation of binary mixtures: the effect of the properties of the component powders on granules).

Opakunle et al. teaches the combination of binary mixtures in the granulating solution and the optimal blends for producing granules of maximum mean size and strength for these mixtures. One of the specific mixtures examined was lactose and citric acid. A number of ratios were utilized that fulfill the claimed ratios and formed granules of various sizes (see Table 1: lactose to citric acid i.e. 90:10, 75:25, 50:50, 25:75, 10:90). Opakunle et al. also teaches that only 10% of the citric acid was required in the mixture to produce granules stronger than those from 100% citric acid, which normally produces stronger granules than lactose singularly. Opakunle et al. also teaches that 5% citric acid in a mixture with lactose greatly enhances granule build up and granule strength. One of skill in the art would immediately envision the method to be useful for other disaccharides including sucrose and trehalose.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gergely (WO 01/51026) as applied to claims 1-4 above, and in view of Wokoff et al. (U.S. Pat. No. 3511914) or Opakunle et al. (The granulation of binary mixtures: the effect of the properties of the component powders on granules).

The teachings of Gergely are addressed above.

Gergely does not expressly teach the ratios of 1:10 to 10:1 and 2:10 to 10:2 (equal to 1:5-5:1), nor the percent of citric acid of the granules. Gergely does teach in his examples solution ratios of 1:12.5 (Example 1), 1:16 (Example 2), and 1:18 (Example 2).

Wokoff et al. teaches that the specific medicaments and specific excipients employed in examples in this art will have many variations in these ingredients that will suggest themselves to those skilled in the art (Col. 3, lines 65-68, Col. 4, lines 1-5). Alternatively, Opakunle et al. teaches the use of lactose and citric acid in a number of ratios which would form granules of various sizes depending on the ratios (see Table 1:

lactose to citric acid i.e. 90:10, 75:25, 50:50, 25:75, 10:90). Opakunle et al. also teaches that 5% citric acid in a mixture with lactose greatly enhances granule build up and granule strength.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the ratios and thereby the percentage of citric acid, as suggested by Wokoff or Opakunle, and produce the instant invention. It would have been obvious to adjust the components of the solution to vary the amount of binding and degree of granulation as needed, to attain the desired results.

One of ordinary skill in the art would have been motivated to do this because it is desirable to modify the degree of binding if a larger or smaller granule is desired by the manufacture to increase the amount of efficiency in the sifting process that regulates size control of the final granules. Modification of the degree of binding will yield greater percentages of the granules of the desired size resulting in higher production of the final product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wokoff et al. (U.S. Pat. No. 3511914) or alternatively, in view of Opakunle et al. (The granulation of binary mixtures: the effect of the properties of the component powders on granules).

The teachings of Wokoff et al. are addressed above.

Wokoff does not expressly teach the percent of citric acid of the granules.

However, Wokoff et al. teaches that the specific medicaments and specific excipients employed in examples in this art will have many variations in these ingredients that will suggest themselves to those skilled in the art (Col. 3, lines 65-68, Col. 4, lines 1-5). Alternatively, Opakunle et al. teaches the use of lactose and citric acid in a number of ratios which would form granules of various sizes depending on the ratios (see Table 1: lactose to citric acid i.e. 90:10, 75:25, 50:50, 25:75, 10:90). Opakunle et al. also teaches that 5% citric acid in a mixture with lactose greatly enhances granule build up and granule strength.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the ratios and thereby the percentage of citric acid, as suggested by Wokoff or in view of Opakunle, and produce the instant invention. It would have been obvious to adjust the components of the solution to vary the amount of binding and degree of granulation as needed, to attain the desired results.

One of ordinary skill in the art would have been motivated to do this because it is desirable to modify the degree of binding if a larger or smaller granule is desired by the manufacture to increase the amount of efficiency in the sifting process that regulates

size control of the final granules. Modification of the degree of binding will yield greater percentages of the granules of the desired size resulting in higher production of the final product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

14. Claims 1-7 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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GH

Zohreh Fay (Primary Examiner)

A handwritten signature in black ink, appearing to read "Zohreh Fay", is written below the printed name.